



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FIKES *et al.*

Appl. No.: 09/458,302

Filed: December 10, 1999

For: **Inducing Cellular Immune  
Responses To  
Carcinoembryonic Antigen  
Using Peptide and Nucleic Acid  
Compositions**

Confirmation No.: 8701

Art Unit: 1644

Examiner: Schwadron, Ronald B.

Atty. Docket: 2060.0080005/HCC/PAC

**Second Supplemental Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450  
Sir:

***Mail Stop Amendment***

Listed on accompanying Forms PTO/SB/08a and PTO/SB/08b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of all U.S. Patents and U.S. Patent Application Publications, cited on Form PTO/SB/08a as documents **AA100-AK100** and **AA101-AK101**, are not provided in accordance with 37 C.F.R. § 1.98(a)(2).

A copy of document **NPL169** cited on Form PTO/SB/08b is not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is *sua sponte* waived where the cited pending application is stored in the USPTO's IFW system."

09/02/2005 JADD01 00000065 09458302

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The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Forms PTO/SB/08a and PTO/SB/08b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes

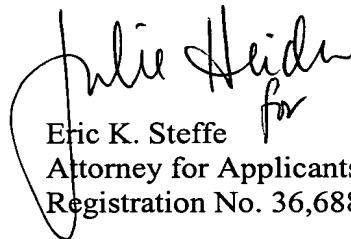
FIKES *et al.*  
Appl. No. 09/458,302

prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

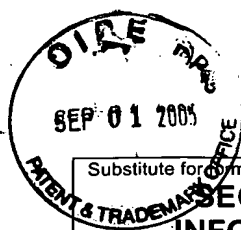
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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Substitute for form 1449A/PTO

**SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete If Known**

Application Number	09/458,302
Filing Date	December 10, 1999
First Named Inventor	John D. FIKES
Art Unit	1644
Examiner Name	Schwadron, Ronald B.
Attorney Docket Number	2060.0080005/HCC/PAC

Sheet	1	of	2
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Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA100	4,235,877	11/25/1980	Fullerton	
	AB100	4,487,715	12/11/1984	Nitecki <i>et al.</i>	
	AC100	4,599,230	07/08/1986	Milich <i>et al.</i>	
	AD100	4,837,028	06/06/1989	Allen	
	AE100	5,013,548	05/07/1991	Haynes <i>et al.</i>	
	AF100	5,128,319	07/07/1992	Arlinghaus	
	AG100	5,736,142	04/07/1998	Sette <i>et al.</i>	
	AH100	5,783,567	07/21/1998	Hedley <i>et al.</i>	
	AI100	6,037,135	03/14/2000	Kubo <i>et al.</i>	
	AJ100	6,413,935	07/02/2002	Sette <i>et al.</i>	
	AK100	6,419,931	07/16/2002	Vitiello <i>et al.</i>	
	AA101	6,602,510	08/05/2003	Fikes <i>et al.</i>	
	AB101	2002/0160960	10/31/2002	Sette <i>et al.</i>	
	AC101	2002/0168374	11/14/2002	Kubo <i>et al.</i>	
	AD101	2003/0143672	07/31/2003	Tangri <i>et al.</i>	
	AE101	2003/0216342	11/20/2003	Fikes <i>et al.</i>	
	AF101	2003/0216343	11/20/2003	Fikes <i>et al.</i>	
	AG101	2003/0224036	12/04/2003	Fikes <i>et al.</i>	
	AH101	2004/0096445	05/20/2004	Sidney <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>4</sup> Kind Code <sup>5</sup> (in known)				
	AL100	EP 0 378 881	06/09/1993	Eniricerche S.p.A.		
	AM100	EP 0 429 816	06/05/1991	F. Hoffmann-La Roche AG		
	AN100	EP 0 433 242	06/19/1991	Fondazione Andrea Cesalpino		
	AO100	WO 93/03764	03/04/1993	Cytel Corporation		
	AP100	WO 94/20127	09/15/1994	Cytel Corporation		
	AQ100	WO 95/07707	03/23/1995	Cytel Corporation		

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## SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

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of

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Application Number

09/458.302

8/1  
Filing Date

December 10, 1999

~~First Named Inventor~~

John D. FIKES

Art Unit

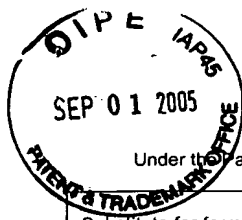
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Examiner Name

Schwadron, Ronald B.

Attorney Docket Number

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<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete If Known</b>		
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			Examiner Name	Schwadron, Ronald B.	
Sheet	1	of	8	Attorney Docket Number	2060.0080005/HCC/PAC

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL81	Alexander, J., et al., "Development of High Potency Universal DR-Restricted Helper Epitopes by Modification of High Affinity DR-Blocking Peptides," <i>Immunity</i> 1:751-761, Cell Press (1994)	
	NPL82	Alters, S.E., et al., "Immunotherapy of Cancer: Generation of CEA Specific CTL Using CEA Peptide Pulsed Dendritic Cells," <i>Dendritic Cells in Fund. And Clin. Immunol.</i> 3:519-524, Plenum Press (1997)	
	NPL83	Arndt, S.O., et al., "Selection of the MHC Class II-Associated Peptide Repertoire by HLA-DM," <i>Immunol. Res.</i> 16:261-272, Humana Press (December 1997)	
	NPL84	Barouch, D., et al., "HLA-A2 Subtypes Are Functionally Distinct in Peptide Binding and Presentation," <i>J. Exp. Med.</i> 182:1847-1856, Rockefeller University Press (1995)	
	NPL85	Bender, A., et al., "Improved methods for the generation of dendritic cells from nonproliferating progenitors in human blood," <i>J. Immunol. Methods</i> 196:121-135, Elsevier Science (1996)	
	NPL86	Ben-Yedidia, T., and Arnon, R., "Design of peptide and polypeptide vaccines," <i>Curr. Opin. Biotechnol.</i> 8:442-448, Current Biology, Ltd. (1997)	
	NPL87	Bremers, A.J.A., et al., "The Use of Epstein-Barr Virus-Transformed B Lymphocyte Cell Lines in a Peptide-Reconstitution Assay: Identification of CEA-Related HLA-A*0301-Restricted Potential Cytotoxic T-Lymphocyte Epitopes," <i>J. Immunother.</i> 18:77-85, Lippincott-Raven (1995)	
	NPL88	Carbone, F.R., and Bevan, M.J., "Induction of Ovalbumin-Specific Cytotoxic T Cells by In Vivo Peptide Immunization," <i>J. Exp. Med.</i> 169:603-612, Rockefeller University Press (1989)	
	NPL89	Carbone, F.R., et al., "Induction of Cytotoxic T Lymphocytes by Primary In Vitro Stimulation with Peptides," <i>J. Exp. Med.</i> 167:1767-1779, Rockefeller University Press (1988)	
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	NPL91	Celis, E., et al., "Epitope selection and development of peptide based vaccines to treat cancer," <i>Semin. Cancer Biol.</i> 6:329-336, Academic Press (1995)	
	NPL92	Deres, K., et al., "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine," <i>Nature</i> 342:561-564, Nature Publishing Group (1989)	
	NPL93	del Guercio, M-F., et al., "Potent immunogenic short linear peptide constructs composed of B cell epitopes and Pan DR T Helper Epitopes (PADRE) for antibody responses in vivo," <i>Vaccine</i> 15:441-448, Elsevier Science (March 1997)	

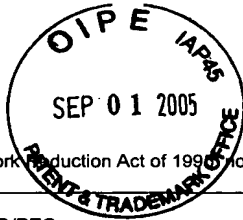
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Sheet	2	of	8	<i>Attorney Docket Number</i>	2060.0080005/HCC/PAC

NON PATENT LITERATURE DOCUMENTS			
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	NPL94	DiBrino, M., et al., "Endogenous Peptides with Distinct Amino Acid Anchor Residue Motifs Bind to HLA-A1 and HLA-B8," J. Immunol. 152:620-631, American Association of Immunologists (1994)	
	NPL95	DiBrino, M., et al., "The HLA-B14 Peptide Binding Site Can Accommodate Peptides with Different Combinations of Anchor Residues," J. Biol. Chem. 269:32426-32434, American Society for Biochemistry and Molecular Biology (1994)	
	NPL96	Donnelly, J.J., et al., "DNA Vaccines," Annu. Rev. Immunol. 15:617-648, Annual Reviews Inc. (April 1997)	
	NPL97	Francis, M.J., et al., "Non-responsiveness to a foot-and-mouth disease virus peptide overcome by addition of foreign helper T-cell determinants," Nature 330:168-170, Nature Publication Group (1987)	
	NPL98	Fynan, E.F., et al., "DNA vaccines: Protective immunizations by parental, mucosal, and gene-gun inoculations," Proc. Natl. Acad. Sci. USA 90:11478-11482, National Academy of Sciences (1993)	
	NPL99	Gileadi, U., et al., "Effect of epitope flanking residues on the presentation of N-terminal cytotoxic T lymphocyte epitopes," Eur. J. Immunol. 29:2213-2222, WILEY-VCH Verlag GmbH (July 1999)	
	NPL100	Golvano, J., et al., "Polarity of immunogens: implications for vaccine design," Eur. J. Immunol. 20:2363-2366, VCH Verlagsgesellschaft mbH (1990)	
	NPL101	Greenberg, P.D., "Adoptive T Cell Therapy of Tumors: Mechanisms Operative in the Recognition and Elimination of Tumor Cells," Adv. Immunol. 49:281-355, Academic Press (1991)	
	NPL102	Gulukota, K., et al., "Two Complementary Methods for Predicting Peptides Binding Major Histocompatibility Complex Molecules," J. Mol. Biol. 267:1258-1267, Academic Press Limited (April 1997)	
	NPL103	Hahn, Y.S., et al., "CD8+ T Cell Recognition of an Endogenously Processed Epitope is Regulated Primarily by Residues within the Epitope," J. Exp. Med. 176:1335-1341, Rockefeller University Press (1992)	
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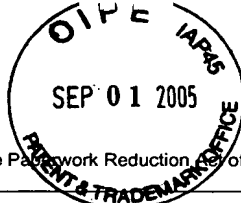
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		<i>Filing Date</i>	December 10, 1999		
		<i>First Named Inventor</i>	John D. FIKES		
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<b>Sheet</b>	<b>3</b>	<b>of</b>	<b>8</b>	<i>Attorney Docket Number</i>	2060.0080005/HCC/PAC

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL105	Hammer, J., et al., "Precise Prediction of Major Histocompatibility Complex Class II-Peptide Interaction Based on Peptide Side Chain Scanning," J. Exp. Med. 180:2353-2358, Rockefeller University Press (1994)	
	NPL106	Hill, C.M., et al., "Exploration of Requirements for Peptide Binding to HLA DRB1*0101 and DRB1*0401," J. Immunol. 152:2890-2898, American Association of Immunologists (1994)	
	NPL107	Huczko, E.L., et al., "Characteristics of Endogenous Peptides Eluted from the Class I MHC Molecule HLA-B7 Determined by Mass Spectrometry and Computer Modeling," J. Immunol. 151:2572-2587, American Association of Immunologists (1993)	
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	NPL110	Jardetzky, T.S., et al., "Peptide binding to HLA-DR1: a peptide with most residues substituted to alanine retains MHC binding," EMBO J. 9:1797-1803, Oxford University Press (1990)	
	NPL111	Kast, W.M., et al., "Protection against lethal Sendai virus infection by in vivo priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide," Proc. Natl. Acad. Sci. USA 88:2283-2287, National Academy of Sciences (1991)	
	NPL112	Kawashima, I., et al., "Identification of HLA-A3-restricted Cytotoxic T Lymphocyte Epitopes from Carcinoembryonic Antigen and HER-2/neu by Primary in Vitro Immunization with Peptide-pulsed Dendritic Cells," Cancer Res. 59:431-435, American Association for Cancer Research (January 1999)	
	NPL113	Keogh, E., et al., "Identification of New Epitopes from Four Different Tumor-Associated Antigens: Recognition of Naturally Processed Epitopes Correlates with HLA-A*0201-Binding Affinity," J. Immunol. 167:787-796, American Association of Immunologists (2001)	
	NPL114	Kondo, A., et al., "Two distinct HLA-A*0101-specific submotifs illustrate alternative peptide binding modes," Immunogenetics 45:249-258, Springer-Verlag (January 1997)	
	NPL115	Kubitscheck, U., et al., "Peptide Binding to Class I Molecules of the Major Histocompatibility Complex on the Surface of Living Target Cells," Scand. J. Immunol. 36:341-348, Blackwell Scientific Publications (1992)	
	NPL116	Kubo, R.T., et al., "Definition of Specific Peptide Motifs for Four Major HLA-A Alleles," J. Immunol. 152:3913-3924, American Association of Immunologists (1994)	

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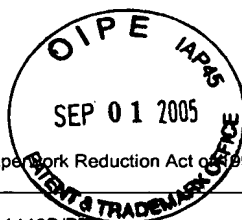
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				Examiner Name	Schwadron, Ronald B.
Sheet	4	of	8	Attorney Docket Number	2060.0080005/HCC/PAC

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	NPL117	Kumar, A., et al., "Universal T Helper Cell Determinants Enhance Immunogenicity of a Plasmodium falciparum Merozoite Surface Antigen Peptide," J. Immunol. 148:1499-1505, American Association of Immunologists (1992)	
	NPL118	Lasarte, J.-J., et al., "Induction of Cytotoxic T Lymphocytes in Mice against the Principal Neutralizing Domain of HIV-1 by Immunization with an Engineered T-Cytotoxic-T-Helper Synthetic Helper Peptide Construct," Cell. Immunol. 141:211-218, Academic Press Inc. (1992)	
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	NPL121	Martinson, F., et al., "Immunization of Mice with Lipopeptides Bypasses the Prerequisite for Adjuvant," J. Immunol. 149:3416-3422, American Association of Immunologists (1992)	
	NPL122	Melief, C.J.M., and Kast, W.M., "Lessons from T Cell Responses to Virus Induced Tumours for Cancer Eradication in General," Cancer Surv. 13:81-99, Cold Spring Harbor Press (1992)	
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	NPL126	O'Sullivan, D., et al., "Characterization of the Specificity of Peptide Binding to Four DR Haplotypes," J. Immunol. 145:1799-1808, American Association of Immunologists (1990)	
	NPL127	O'Sullivan, D., et al., "On the Interaction of Promiscuous Antigenic Peptides with Different DR Alleles," J. Immunol. 147:2663-2669, American Association of Immunologists (1991)	

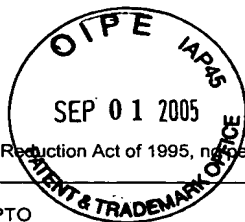
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			<i>First Named Inventor</i>	John D. FIKES	
			<i>Art Unit</i>	1644	
			<i>Examiner Name</i>	Schwadron, Ronald B.	
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	NPL128	Panina-Bordignon, P., et al., "Universally immunogenic T cell epitopes: promiscuous binding to human MHC class II and promiscuous recognition by T cells," Eur. J. Immunol. 19:2237-2242, VCH Verlagsgesellschaft mbH (1989)	
	NPL129	Paz, P., et al., "Discrete Proteolytic Intermediates in the MHC Class I Antigen Processing Pathway and MHC I-Dependent Peptide Trimming in the ER," Immunity 11:241-251, Cell Press (August 1999)	
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	NPL132	Rahemtulla, A., et al., "Normal development and function of CD8+ cells but markedly decreased helper cell activity in mice lacking CD4," Nature 353:180-183, Nature Publishing Group (1991)	
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	NPL135	Reitermann, A., et al., "Lipopeptide Derivatives of Bacterial Lipoprotein Constitute Potent Immune Adjuvants Combined with or Covalently Coupled to Antigen or Hapten," Biol. Chem. Hoppe Seyler 370:343-352, Walter De Gruyter (1989)	
	NPL136	Restifo, N.P., et al., "Antigen Processing In Vivo and the Elicitation of Primary CTL Responses," J. Immunol. 154:4414-4422, American Association of Immunologists (1995)	
	NPL137	Saper, M.A., et al., "Refined Structure of the Human Histocompatibility Antigen HLA-A2 at 2.6 Å Resolution," J. Mol. Biol. 219:277-319, Academic Press Ltd. (1991)	
	NPL138	Schaeffer, E.B., et al., "Relative contribution of 'determinant selection' and 'holes in the T-cell repertoire' to T-cell responses," Proc. Natl. Acad. Sci. USA 86:4649-4653, National Academy of Sciences (1989)	

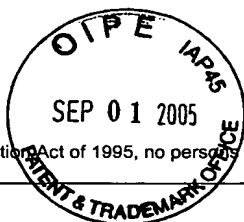
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		<i>Examiner Name</i>	Schwadron, Ronald B.		
<b>Sheet</b>	6	<b>of</b>	8	<i>Attorney Docket Number</i>	2060.0080005/HCC/PAC

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	NPL139	Schumacher, T.N.M., et al., "Peptide selection by MHC class I molecules," Nature 350:703-706, Nature Publishing Group (1991)	
	NPL140	Sette, A., and Sidney, J., "HLA supertypes and supermotifs: a functional perspective on HLA polymorphism," Curr. Opin. Immunol. 10:478-482, Current Biology Publications (August 1998)	
	NPL141	Sette, A., et al., "A Novel Approach to the Generation of High Affinity Class II-Binding Peptides," J. Immunol. 145:1809-1813, American Association of Immunologists (1990)	
	NPL142	Sette, A., et al., "Effect of Conformational Propensity of Peptide Antigens in Their Interaction with MHC Class II Molecules," J. Immunol. 143:1268-1273, American Association of Immunologists (1989)	
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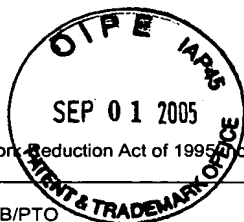
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	NPL153	Sugawara, S., et al., "A simple method to eliminate the antigenicity of surface class I MHC molecules from the membrane of viable cells by acid treatment at pH 3," <i>J. Immunol. Methods</i> 100:83-90, Elsevier Science (1987)	
	NPL154	Tam, J.P., and Lu, Y-A., "Vaccine engineering: Enhancement of immunogenicity of synthetic peptide vaccines related to hepatitis in chemically defined models consisting of T- and B-cell epitopes," <i>Proc. Natl. Acad. Sci. USA</i> 86:9084-9088, National Academy of Sciences (1989)	
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	NPL157	von Boehmer, H., and Haas, W., "Distinct Ir Genes for Helper and Killer Cells in the Cytotoxic Response to H-Y Antigen," <i>J. Exp. Med.</i> 150:1134-1142, Rockefeller University Press (1979)	
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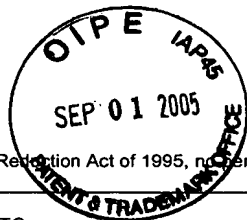
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	NPL160	Wherry, E.J., et al., "The Induction of Virus-Specific CTL as a Function of Increasing Epitope Expression: Responses Rise Steadily Until Excessively High Levels of Epitope Are Attained," J. Immunol. 163:3735-3745, American Association of Immunologists (October 1999)	
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